REMARKS

Applicants have carefully reviewed the Notice of Non-Compliant Amendment mailed August 12, 2008, and thank Examiner Rogers for the detailed review. In response to the Notice, Applicants have amended the claims to include the text of withdrawn Claims 38-44. By way of this amendment, no new matter has been added.

Applicants have carefully reviewed the Office Action mailed January 17, 2008, and again thank Examiner Rogers for his review of the pending claims. Claims 1, 6, 7, 10-17, 21, 23-32, 35, and 37-44 were pending. Claims 38-44 were withdrawn from consideration, leaving Claims 1, 6, 7, 10-17, 21, 23-32, 35 and 37 pending. Those claims were rejected in the Office Action. In this response, claims 1, 17, 23, 25, 26, and 27 are amended. No new claims or new subject matter are added.

At least for the reasons set forth below, Applicants respectfully traverse the rejections. Further, Applicants believe that there are also reasons other than those set forth below why the pending claims are patentable and reserve the right to set forth those reasons, and to argue for the patentability of claims not explicitly addressed herein, in future papers. Applicants respectfully request reconsideration of the present application in view of the above amendments and the following remarks.

Election/Restrictions

Applicants acknowledge receipt of the Examiner's comments that led to the withdrawal of Claims 38-44.

Rule 132 Affidavit

Applicants acknowledge receipt of the Examiner's comments concerning the receipt of the previous Rule 1.132 affidavit of Dr. Timothy Becker.

Claim Rejections under 35 U.S.C. §112

The Examiner rejected claims 1, 6-7, 10-17, 21, 23-32, and 35 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement due, *inter alia*, to the use of the word "about" to describe the claimed molecular weight range. The rejection is respectfully traversed. Claims 1, 17, 23, 25, 26, and 27 have been amended in this response to

remove the word "about". Applicants thank the Examiner for the indication that support for the range 65,000 to 200,000 is found in the application.

The Examiner rejected claims 1, 17, 23, and 25-27 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reason that the molecular weight range was unitless. The rejection is respectfully traversed. Claims 1, 17, 23, and 25-27 have been amended in this response to state the units "g/mol." Support for the amendment is found throughout the specification; *see* for example, Par. 0016.

Therefore, Applicants respectfully request withdrawal of all Section 112 rejections and allowance of Claims 1, 17, 23, and 25-27 and their respective dependent claims.

Claim Rejections under 35 U.S.C. §103

The Examiner rejected claims 1, 6-7, 10-17, 21, 23, 24, 26, 35, and 37 under 35 U.S.C. §103(a) as allegedly being unpatentable over Cochrum (U.S. 5,614,204)("Cochrum") in view of Becker ("Application of Calcium Alginate as an Endovascular Embolization Material for Vascular Lesions," Dissertation, Arizona State University)("Becker"). The Examiner also rejected claims 1, 6, 7, 10-17, 21, 23-32, 35, and 37 under 35 U.S.C. §103(a) as allegedly being unpatentable over Cochrum in view of Becker in view of Ji et al. (U.S. 5,894,022) ("Ji") in view of Reeves (U.S. 5,222,970)("Reeves"). Due to commonality in the rejections concerning the claimed molecular weight range, all Section 103(a) rejections are addressed together herein. The rejections are respectfully traversed.

It is well known that "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. *Accord* M.P.E.P. § 706.02(j). Moreover, the mere fact that references can be combined or modified does not render the resulting combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F2d 680, 16 U.S.P.Q 2d 1430 (Fed. Cir. 1990).

MPEP Section 2143 sets forth the basic requirements for the Patent and Trademark Office to establish *prima facie* obviousness as follows: "To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references

themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

The case law "makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for showing of the teaching or motivation to combine prior art references." *In re Dembiczak,* 175 F.3d 994, 999 (Fed. Cir. 1999); see *also Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665 (Fed.Cir. 2000) This is because "[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight." *Dembiczak,* 175 F.3d at 999. Thus, it is established law that one "cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Ecolochem, Inc. v. Southern Cal. Edison Co.*, 227 F.3d 1361, 1371, 56 USPQ2d 1065 (Fed. Cir. 2000) (citing *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1780, 1783 (Fed. Cir. 1988)).

In this response, independent claims 1, 17, 23, 25, 26, and 27 have been amended to include the limitation "wherein the purified alginate liquid is of molecular weight from 65,000 g/mol to 200,000 g/mol." None of the cited references - Cochrum, Becker, Reeves, or Ji - teaches or discloses this limitation. For at least this reason, claims 1, 17, 23, 25, 26, and 27, and their respective dependent claims, are not obvious in light of the cited references. The rejections should therefore be withdrawn and the claims allowed as amended.

The Office Action asserts, *inter alia*, that Becker discloses the claimed molecular weight range. However, for at least the reasons discussed herein, Applicants respectfully state that Becker does not support this assertion, and the Examiner has failed to show a *prima facie* case of obviousness based on any combination including Becker.

At pages 6-8 of the Office Action, the Examiner makes certain statements and assumptions concerning the alginates discussed in Becker. As some examples, the Examiner cites Becker with respect to the use of purified high guluronic acid content (PHG) purchased from Pronova. (Page 6). The Examiner also cites to certain Novamatrix online catalog materials for the proposition that

"Pronova UP-LVG is known to have a molecular weight range of 75,000 to 200,000 g/mol, within applicants [sic] claimed range." (*Id.*) The Examiner also states that "[r]egarding claims 35 and 37 since the PHG alginates of Becker are the same as the alginates claimed by applicants it is obvious that the same polymer will have the same properties including viscosity." (Page 8)(emphasis added). The Examiner also states that "[a]lso on page 30 of the dissertation a figure of viscosity vs. concentration shows that at 1 wt% PHG appears to have a viscosity less than 25cP." (*Id.*) The Examiner then concludes, along with other comments, that the invention as claimed is obvious.

However, as discussed herein, the Examiner's conclusions are based on assumptions that are inaccurate and unsupported. For at least the reasons stated herein, including without limitation, in the accompanying additional copy of the previously filed Declaration under 37 CFR § 1.132 of inventor Timothy A. Becker, Ph.D. ("Becker Decl.," Exhibit A, which is hereby incorporated in full), the rejections are respectfully traversed.

Dr. Becker is the first named inventor on the present application and is the author of his own doctoral dissertation. With respect to the source and nature of the alginates, the work underlying Dr. Becker's dissertation was the same as the work underlying a previous cited reference, U.S. 2001/0031978 A1 ("the Kipke application"), in which Dr. Becker is also named co-inventor. The Kipke application was filed in February 2001 before the approval of Dr. Becker's doctoral dissertation in May 2001. In Dr. Becker's previous October 2007 Declaration under 37 CFR §1.132 submitted in this matter, he explained why the Examiner's conclusion that the alginates used in Dr. Becker's previous work were the same as the alginates disclosed in the present application was unsupported. Dr. Becker's previous comments apply here as well. (Pars. 1, 2, 4, and 6 of Becker Decl.)

As Dr. Becker explains based on his knowledge of the technology disclosed and discussed in Becker and the present application, the alginates discussed in Becker, the Kipke application, and the present application were purchased from the same source, Pronova. However, no characterization of molecular weight was available from the vendor on the batches of alginate used at the time of Dr. Becker's doctoral work and dissertation. The only known characterization was the G-acid content and the purity. Therefore, the optimization of alginates discussed in Becker originally focused on G acid content and purity only. All testing disclosed in Becker was done with the same batches of

alginate. The purified, high G-acid (PHG) batch of alginate was identified as optimal in Becker. (Pars. 4 and 7 of Becker Decl.)

Subsequently, when the original batch of PHG alginate was exhausted, a new batch of the PHG-class of alginate was ordered from Pronova. The new PHG batch of alginates was made to the specifications disclosed in Becker. However, Dr. Becker found that the resulting injectable liquid viscosity and final gel strength were significantly different from the original properties disclosed in his doctoral dissertation. The vendor had sent the same class of alginate (PHG), however, the original batch of PHG alginate was no longer available. In addition, Dr. Becker found that although Pronova had begun classifying the new batches of PHG alginates by their molecular weight, this information was not available for the original batch of PHG alginate. Thus, as Dr Becker found, the MW of the alginate material in Becker is unknown. (Par. 8 of Becker Decl.)(emphasis added).

The Examiner's statements, based on the Novamatrix online catalog materials, that "Pronova UP-LVG is known to have a molecular weight range of 75,000 to 200,000 g/mol, within applicants [sic] claimed range" has no bearing on the MW of the alginate disclosed in Becker because the information cited by the Examiner relates only to present knowledge about the molecular weight of certain types of Pronova UP-LVG sold currently by Novamatrix. Based the Novamatrix online documents cited by the Examiner, there is no proof of when that molecular weight information was first made publicly available through those documents. Stated another way, the Examiner has not demonstrated that the molecular weight of the PHG used in Becker, or knowledge of that molecular weight, was known at any time before the present application was filed. (Par. 9 of Becker Decl.) Consequently, the Examiner has failed to show a *prima facie* case of obviousness under Section 103 based on any combination of Becker with any other references, and the rejections should be withdrawn.

Moreover, as Dr. Becker states, without a way to determine the molecular weight of the alginates used on Dr. Becker's doctoral work, part of his original work underlying the present application was to characterize the entire range of PHG alginates then currently available from Pronova. In doing so, Dr. Becker and co-workers discovered the properties of the molecular weight ranges disclosed and claimed in the present application. (Par. 10 of Becker Decl.)

With respect to the Examiner's comments concerning the figure on page 30 of Becker, Applicants respectfully disagree with the assertion that the figure "shows that at 1 wt% PHG appears to have a viscosity less than 25cP." The figure was not prepared to disclose such information, and the figure is the same figure as Figure 7a in the related Kipke et al. patent, U.S. Patent 6,592,566, where the Figure clearly shows the distinction from present claims 35 and 37. In addition, data on which the figure is based are set out in Table 2.2 at page 27 of Dr. Becker's doctoral dissertation, which clearly shows the complete lack of any viscosity data related to 1% PHG. (Par. 11 of Becker Decl.)

As shown by the facts in Dr. Becker's Declaration and elsewhere, the assumption in the Office Action that the same alginates with the same molecular weights were used in both Becker and the present application is not supportable. In fact, for the reasons discussed herein, Becker does not teach or disclose the molecular weight limitation as claimed, nor can such disclosure be assumed merely because the same vendor was disclosed in Becker and the present application. This deficit is not cured by any of the other cited references. Because at least this novel element is lacking in the cited references, the attempted combination of Becker with any other cited reference – Cochrum, Reeves, or Ji - fails to support a *prima facie* case of obviousness. For at least these reasons, all rejections under Section 103(a) should be withdrawn, and all rejected claims should be allowed as written or amended.

CONCLUSION

In view of the above, the pending claims are believed to be in condition for allowance. Accordingly, reconsideration and allowance are respectfully requested and the Examiner is respectfully requested to pass this application to issue.

Any fees associated with the filing of this paper have already been identified in the transmittals accompanying this paper. However, if any additional fees are required in connection with the filing of this paper that are not identified in any accompanying transmittals, permission is given to charge Deposit Account 18-0013, under order number 65306-0092 in the name of Rader, Fishman and Grauer PLLC. To the extent necessary, a petition for extension of time under 37 C.F.R. §1.136 is hereby made, the fee for which should also be charged to this Deposit Account.

If the Examiner has any questions or comments, the Examiner is kindly urged to call the undersigned to facilitate prosecution.

Dated: October 14, 2008

Respectfully submitted,

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